Site visit inspection report on compliance with HTA minimum standards

Miller House Mortuary

HTA licensing number 12125

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

12 April 2012

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Miller House Mortuary (the establishment) had met the majority of the HTA standards, shortfalls were found, particularly in relation to Governance and Quality Systems. These shortfalls are similar to those identified at the previous inspection and highlight the need for continual review and development of practices. The high level of activty in the mortuary and small number of staff are felt to have contributed to administrative and governance tasks being given less priority than other tasks and, whilst assistance has been sought from administrative staff from other areas of the Local Authority, they lack the necessary experience to critically review the mortuary systems.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Paragraph 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

Miller House Mortuary carries out approximately 1300 post-mortem (PM) examinations each year, the majority of which are carried out under the authority of the Coroners in the local area and approximately 60-70 of which are forensic cases. Known high-risk PM examinations are undertaken and there is a separate purpose built post-mortem room used for these. PM examinations requiring the consent of the bereaved or involving paediatric cases are not undertaken at the establishment. Since consent is not taken by establishment staff and tissues are disposed of, if applicable, at the the establishments carrying out histological or toxicological analysis, the standards relating to consent and disposal are not applicable.

This was the second routine inspection of the establishment, the first one having been undertaken in 2009. Following the previous inspection, conditions were placed on the licence in relation to the lack of audits and risk assessments as part of the governance system, the lack of mandatory and developmental training of staff and the lack of documented policies and procedures. These conditions on the licence were met shortly after the inspection and, notwithstanding the identification of shortfalls this time round, a significant improvement was noted in compliance with HTA minimum standards.

The inspection comprised interviews with members of staff, a review of relevant documentation and visual inspection of the mortuary and body storage area. An audit was carried out on the body store, during which the details on the wrist bands of two of the deceased, one of which was located in the long term frozen storage, were compared with corresponding details in the mortuary register. No anomalies were found. An audit was also carried out on the records of samples taken during PM examinations. Five sample collection forms were checked against entries from the specimen book; two of the samples were for histology and were recorded in the register book, the others were not (refer to shortfall GQ6).

Inspection findings

The HTA found the Designated Individual and the Corporate Licence Holder, Greenwich Council, to be suitable in accordance with the requirements of the legislation. The inspection team also assessed the suitability of the new corporate licence holder contact and found them to be suitable for the role.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	SOPs have been recently reviewed, but a few examples were identified where the current procedure deviates from that documented or contains an error, such as: the use of portable racking for contingency storage space as opposed to historical practices of placing the deceased on the floor; the use of names on the fridge doors, which has been discontinued; and the thawing at 4 degrees Celsius of bodies that have been in long term storage rather than the documented 40 degrees Celsius. There is a lack of audit of compliance with procedures, which may have contributed to the discrepancies in the SOPs going unnoticed. Not all SOPs have the version number and date of next review on them.	**Minor**
GQ2 There is a documented system of quality management and audit		
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills	Standardised essential courses, such as training in manual handling and COSHH have not been provided for staff working in the mortuary.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Several minor shortfalls relating to deficiencies in the identification and traceability of the deceased and relevant material removed from the deceased combine to make a major shortfall against this standard. The establishment's staff identify the deceased prior to post-mortem examination and release of the body to funeral directors based on first name and surname alone and therefore there is a risk of mis-identification of the deceased if there were two individuals with the same or similar names. **Minor shortfall** A unique identifier is recorded in the	**Major**

	mortuary register and a wrist tag with the corresponding number is placed on the deceased; however, this number only verifies the deceased with the entry in the mortuary register and is not used for any other identification procedures. **Minor shortfall.** Records are maintained for histology specimens which are sent to another establishment for processing and analysis; however no similar record exists for blood and urine samples which are sent for toxicological analysis, or for organs sent for specialist analysis. The establishments to which samples (histology, toxicology, organs) are sent are not recorded. When tissue is returned to the mortuary for repatriation with the deceased, the appropriate record in the log book is annotated with a date. However, it is not clear if this means the tissue has been returned or if this is the date of repatriation as well, since this is not a standardised practice. **Minor shortfall.** There is no formal procedure to ensure that tissue is repatriated in line with the wishes of the bereaved. Staff occasionally annotate the mortuary register to indicate repatriation has been carried out, but this is not a formalised process and there is a risk of releasing the body without repatriation of tissues. Furthermore, mortuary staff rely on the coroner not to issue the cremation or burial form until the organs have been repatriated, but there is no system to verify this is the case. The coroner's officer highlights in the mortuary register names of the deceased which are ready for release, mortuary staff cross check those highlighted against release forms for cases from one of the coroner's they work with but not otherwhich means any erroneous highlighting would not be picked up. **Minor shortfall.**	

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	A number of risk assessments have been carried out but these are predominantly assessments of risks to the health and safety of staff and have been carried out by staff who do not work in the mortuary and do not have indepth knowledge of mortuary practice. Risks associated to the security and dignity of the deceased, traceability of bodys and body parts and identification of bodies have not been assessed. In some instances there is a lack of preventative measures in place to ensure identified risks are mitigated. Occupational health screening is not provided by the establishment and individuals are left to pursue this themselves.	**Minor**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1	Due to the small size of the mortuary team, information is usually shared informally. Establishment staff are encouraged to hold more formalised meetings where minutes are taken so that when issues are discussed and actions are agreed, they can be used as a reference to ensure progress is made.
2.	GQ1	The DI is advised to implement a more formalised procedure for notifying staff of changes to SOPs and record that staff have read and agreed to adhere to SOPs.
3.	GQ2	The DI is advised to include the outcome actions in the reports of the scheduled audits undertaken to provide closure to the audit process and illustrate the improvements which have been made.
4.	GQ3	The DI is advised to ensure that staff carrying out licensable acitivities are subject to formal staff appraisal to ensure any shortcomings in competency or development needs are recognised and acted upon.
5.	GQ4	The DI is advised to consider archiving registers or other record books which contain data spanning several years in order to reduce the risk of all data being lost or destroyed in one go.
6.	GQ6	A red sticker is added to the mortuary register for deceased with same or similar names. The DI is advised to use this prompt on the wrist tag of the deceased and any other relevant documents, such as the PM request form, to ensure additional care is taken to identify the deceased correctly.
7.	GQ7	The DI is advised to include the reporting of serious untoward incidents (SUI) to the HTA in the critical incident reporting protocol. This should include details as to what constitutes a SUI, how it should be reported and the time frame specified by the HTA.

8.	PFE5	Due to the high level of post-mortem activity, up to six PM examinations are carried out at once; the DI is advised to consider the use of colour coding or numbering of containers for holding organs and corresponding tables, as an additional precaution against the risk of organs going back into the wrong deceased.

Concluding comments

During the inspection a number of areas of good practice were identified. The mortuary has a high level of security with controlled entry systems, pressure sensors on the roof and CCTV. It is situated within a residential area, which means the main entrance through which the deceased are brought into the body store is overlooked; to prevent anyone seeing the deceased being moved between the vehicle and the premises, an opague plastic slatted screen has been installed, through which funeral directors partially reverse their vehicle.

Detailed plans have been made to prepare the mortuary in the event of a disaster in the local area. Additional refrigerated body storage and screening have been identified and can be supplied at short notice, and procedures and contingency plans involving other local HTA licensed mortuaries have been agreed.

The establishment carries out a high level of PM examinations, particularly in respect to the small team of staff, yet compliments were noted on the high standard of reconstruction of deceased that have undergone trauma and PM examinations for the benefit of the bereaved during viewings. The staff are also mindful to preserve the dignity of the deceased and utilise cloths within the PM room to provide a modesty cover.

There are a few areas of practice that require improvement, including one major shortfall and three minor shortfalls. Since the last inspection, the establishment has made marked progress in the development of its quality management systems. However, the HTA has identified that there is room for further improvement in these areas, with particular regard to systems and records of traceability. The HTA has given advice to the Designated Individual with respect to making processes more robust to help prevent a SUI occurring and documenting the procedure for notifying the HTA of a SUI. Advice has also been given to ensure meetings are minuted and that actions following audits or risk assessments are recorded, so that it is evident that timely progress is made and actions completed.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 02 May 2012

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 13 June 2012

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 24 December 2012

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat

errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.

- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.